

ASPAR
Ibucalm 400mg Tablets P
(contains Ibuprofen)

Docment Information

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Read this leaflet carefully before taking your medicine. It does not contain all the information about your medicine that you may need to know, so please ask your doctor or pharmacist if you have any questions. This leaflet only applies to Ibucalm 400mg tablets.



1. WHAT THESE TABLETS DO

Ibucalm contains Ibuprofen which is a type of painkiller called a 'non steroidal anti inflammatory drug' (NSAID). It is used to relieve rheumatic and muscular pain, pain of some arthritic conditions, backache, neuralgia, migraine, headache, dental pain, period pains, feverishness and the symptoms of cold and flu.



2. CHECK BEFORE YOU TAKE

Do not take these tablets if you:

- Are allergic to Ibuprofen or any of the other ingredients listed in section 6
- Have a history of allergy to aspirin, ibuprofen or NSAID's which includes attacks of asthma, swelling of the nose and throat, skin rashes or a runny nose.
- Have an active or a history of recurrent peptic ulcers (more than two).
- Are over six months pregnant
- Are already taking aspirin at doses of above 75mg daily or taking any other NSAID
- Have severe liver, kidney or heart problems
- Have a history of gastro intestinal bleeding or perforation related to the use of NSAID's

Warnings and Precautions

Anti-inflammatory pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

If you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack 'TIA') or think that you may be at risk have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

Take special care and tell your doctor if you:

- Suffering from Systemic Lupus Erythematosus (SLE) a condition of the immune system affecting connective tissue resulting in joint pain, skin change and disorders of other organs
- Have inflammatory bowel disease (e.g. Crohns disease, Ulcerative colitis) as it could get worse
- Have kidney problems as these can get worse
- Have a history of asthma or allergies

Taking other medicines

Ibucalm 400mg Tablets may affect or be affected by some other medicines. For example:

- Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/ acetylsalicylic acid, warfarin, ticlopidine)
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)

Some other medicines may also affect or be affected by the treatment of Ibucalm 400mg Tablets. You should therefore always seek the advice of your doctor or pharmacist before you use Ibucalm 400mg Tablets with other medicines.

Tell your doctor or pharmacist if you are already taking any of the following medicines:

- Diuretics (such as furosemide and triamterene) or beta blockers (such as atenolol and propranolol) for high blood pressure
- Blood thinning medicines that prevent blood clotting e.g. Warfarin
- Low dose aspirin (up to 75mg daily)
- Taking other medicines such as corticosteroids, anti platelet agents, cardiac glycosides, selective serotonin reuptake inhibitors (SSRIs), methotrexate, ciclosporin, mifepristone, tacrolimus, zidovudine or quinolone antibiotics

Children and adolescents

There is a risk of renal impairment in dehydrated children and adolescents.

Pregnancy and breast-feeding

Tell your doctor before taking these tablets if you are pregnant or think you may be pregnant. Ibuprofen belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that Ibuprofen, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Medicines such as ibuprofen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the feet or hands due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack 'TIA') or think you may be at risk of these conditions (for example: if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.



3. HOW TO TAKE THE TABLETS

Ibucalm is only for short term use. Do not take Ibucalm for longer than 10 days.

Take the lowest dose for the shortest time necessary to relieve your symptoms.

If symptoms persist or worsen consult your doctor.

Dosage in adults, the elderly and children over 12 years:

Take 1 tablet every 4 to 8 hours. Do not take more than 3 tablets in 24 hours.

Take the tablet with food and swallow whole with a drink of water.

Do not give these tablets to children under 12 years old except on the advice of a doctor.

If in adolescents this product is required for more than 3 days or if symptoms worsen a doctor should be consulted.

Seek medical attention **IMMEDIATELY** if you accidentally take too many tablets.

If you miss a dose, do not take a double dose to 'make up' for the missed dose.



4. POSSIBLE SIDE EFFECTS

Ibucalm can cause side effects. These can be minimised by taking the smallest possible dosage.

Serious side effects

If you suffer from any of the below, at any time during your treatment STOP TAKING the medicine and seek medical help.

- Pass blood in your faeces (stools or motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds
- Breathing difficulties such as shortness of breath and wheezing that may lead to dizziness
- Swelling of the face, tongue or throat
- Skin reactions including itchy, patchy, red or raised skin rash and very rarely skin blistering or peeling
- Indigestion, heartburn or stomach pains
- STOP TAKING the medicine and tell your doctor if you experience:
Indigestion or heartburn, abdominal pain (pains in your stomach) or other abnormal stomach symptoms.

Other side effects

Uncommon reactions: Stomach pain or indigestion, feeling sick, headache

Rare: Diarrhoea, flatulence, constipation and vomiting.

Very rare reactions: Severe problems with your gut (bleeding, perforation, ulcer), worsening of ulcerative colitis and Crohns disease, kidney problems, liver disorders, changes in the blood which may lead to fever, sore throat, mouth ulcers, flu-like symptoms, tiredness and unexplained bleeding/bruising

Ibuprofen may slightly increase the risk of heart attack or stroke.

If you experience any of these or any other side effects and they get serious, contact your doctor or pharmacist.



5. STORING YOUR MEDICINE

- Keep out of the sight and reach of children
- Do not store above 25°C.
- Do not use after the 'expiry' date shown on the carton.
- The tablets should be stored in the original packaging to protect from moisture.



6. MORE ABOUT YOUR MEDICINE

The active ingredient in Ibucalm tablets is Ibuprofen. They are round and pink in colour.

The inactive ingredients are Colloidal anhydrous silica, starch, povidone, croscarmellose sodium, microcrystalline cellulose, alginate acid, magnesium stearate, sodium lauryl sulphate, sodium starch glycolate, talc, hypromellose (E464), glycerol, carmine (E120) and titanium dioxide (E171).

The product licence holder and manufacturer responsible for release is:

Aspar pharmaceuticals Ltd., Capitol way, Colindale, London NW9 0EQ

P.L. 08977/0017

The tablets are available in blister packs of 24, 48 and 96